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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/546,095

06/16/2006

Katsuhiko Suzuki

105-89 PCT/US

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EXAMINER

ELLIS, SUEZU Y

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

02/07/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/546,095	Applicant(s) SUZUKI, KATSUHIKO	
	Examiner Suezu Ellis	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 August 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8/18/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on August 18, 2005 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

Claims 1, 2 and 4 are objected to because of the following informalities:

In claim 1, line 4, claim 2, lines 1-2, and claim 4, line 5, claim language recites "at least one or two or more selected from...". The phrase "at least one" is sufficient since the "or two or more" is redundant.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 4, claim language recites a "mass ratio of a shell to a filler material of the seamless capsule is 5:95 to 70:30". It appears the filler material is considered everything but the shell, since it adds up to 100%. However, further in claim 4, claim language recites "a core liquid that includes the filler material". Therefore, it is unclear if the core liquid minus the filler material is taken into account of the ratios stated above, since in this instance, the ratio would be based on more than 100%. Please clarify.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakamura et al. (WO 02/13819) in view of Kondo (JP 2001-89362). Hereinafter, US 2003/0195246 will be referenced as an English language equivalent of WO 02/13819.

With respect to claims 1, 2 and 4, Nakamura et al discloses a method of forming seamless soft capsule using a SPHEREX capsule filling machine. Applicants use the

same apparatus in their example at page 25 of the specification. Therefore, the capsule filling apparatus of Nakamura et al. is considered to have the same set up as applicant's. The capsule shell comprises a shell material (gelatin) with a plasticizer (glycerin or polyethylene glycol) [0032], [0033]. The capsule is by weight 20% shell and 80% filling and approximately 8.5 mm (see Example 1 and 2). The capsules are hardened in a coolant liquid (hardening liquid), removed from the liquid, washed with a solvent and dried (Examples 1 and 2). Nakamura et al. fails to expressly disclose the inclusion of a crystallization agent. Kondo et al. discloses in a seamless capsule comprising a crystallizing agent (xylitol) where the crystals are formed by precipitated to the external surface of the shell (wrapper) when the shell is hardened [0014], [0018], [0021], [0022], [0024], [0026]. Kondo et al. further discloses the shell has white crystals that are uniform on the external surface, therefore is considered to create an opaque shell [0025], [0026]. It would have been obvious to one of ordinary skill in the art to modify the seamless capsule of Nakamura et al. to include a crystallizing agent in order to provide seamless capsules that can be swallowed easily, broken down physically by the teeth and the taste can be tasted instantaneously without dissolving, while decreasing the likelihood of the capsules adhering over time [0008], [0026].

With respect to claims 3 and 5, the modified Nakamura et al. fails to expressly disclose the crystallization agent being 10-80% by mass based on the total amount of the shell, excluding water. Kondo et al. discloses the weight ratio of crystallization agent to the surplus is a matter of design choice [0013], [0016], [0017] Kondo et al. further discloses an example where the ratio of xylitol to the surplus part (minus the

xylitol) can be 40-200 to 130 [0016]. It would have been obvious to one of ordinary skill in the art to modify the weight ratio of the crystallizing agent to the total amount of the shell in order to optimize the desired properties [0008], [0026]. Further, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Suzuki et al. (US 5,882,680) discloses a method of producing seamless capsules.

Telephone/Fax Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suezu Ellis whose telephone number is (571) 272-2868. The examiner can normally be reached on 8:30am-5pm (Monday-Friday).

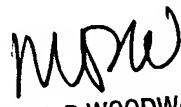
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SE


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